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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,969	12/14/2001	Richard A. Pittner	24001-010	7314

7590

08/16/2002

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EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/016,969

Applicant(s)

PITTNER ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,13-22,24-28 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-12,23,29 and 31-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 and 6.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicants' election with traverse of Group I (Claims 1-19, 23-32, and 33) and species "obesity" in Paper No. 5 filed upon 07/16/2002 is acknowledged. The traversal is on the grounds (i) that the subject matter of Group II is directed to improve lipid profile or treating dyslipidemia and thus fall into the realm of Group I; and (ii) that all the disclosed species, although distinct, are related, and search and the examination of the entire application can be made without a serious burden on the Patent Office. This has been fully considered but is not deemed to be persuasive because the two groups of inventions are drawn to two completely different methods each having completely different method steps and outcomes. In addition, dyslipidemia is one of seven distinct species of disorder and applicants have elected "obesity" in response to species election. Thus, examination of the entire application, both groups and all the disorder species, requires non-cohesive searches and consideration, which constitutes an undue burden on the Examiner. Even if the relevant prior art for all the inventions can be done in a single search, examination of the entire inventions still requires separate consideration and thus constitutes an undue burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-33 are pending. Claims 1, 4-12, 23, 29 and 31-33 are under consideration. All other claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention (both group and species).

**Priority**

3. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 119(e) to a provisional application, 60/256,216, filed upon 12/14/2000.

**Drawings**

4. The drawings filed on 12/14/2001 are accepted by the Examiner.

**Claim Rejections—35 USC § 103**

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 4, 4-12, 23, 29, and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malaisse-Lagae et al. (*IDS, Experientia* 33:915-917, 1977) in view of both Yoshinaga et al. (*IDS, Am. J. Physiol.* 263:G695-701, 1992) and Allen et al. (*IDS, Digestion* 30:255-262, 1984).

Malaisse-Lagae et al. teach a method of treating obesity comprising administering to obese mice a therapeutic effective amount of pancreatic

polypeptide (See, e.g., Abstract). Peripherally administration of 5  $\mu\text{g/kg}$  body weight per dose or 50  $\mu\text{g/kg}$  body weight per dose (two daily injections) reduced food intake and suppressed body weight (Page 916).

Malaisse-Lagae et al. fail to teach (i) the use of peptide YY (PYY) or PYY agonist, e.g., PYY[3-36]; (ii) the relative potency of a PYY agonist and NPY.

Yoshinaga et al. teach the structural requirements of peptide YY for inhibition of pancreatic exocrine, gastric acid, and insulin secretion (See, e.g., Abstract). Yoshinaga et al. also teach the effects of PYY and PYY-related peptides, including a PYY agonist, PYY[3-36], and [Leu31, Pro34]NPY on gastric acid output. Yoshinaga et al. show that PYY has a greater potency than [Leu31, Pro34]NPY in gastric emptying assay (e.g., Fig. 2 and Table 3).

Allen et al. teach that infusion of PYY resulted in a significant delay in gastric emptying of glucose, whereas infusion of NPY at the same rate had no significant effect on the rate of gastric emptying (See, e.g., Abstract). Combining the teaching of Yoshinaga et al. with the teaching of Allen et al., it is reasonably assumed that PYY[3-36] has a greater potency than NPY in gastric emptying assay.

Therefore, It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the PYY and a PYY agonist, e.g., PYY[3-36], in the method of treating obesity as taught by Malaisse-Lagae et al. with a reasonable expectation of success. One would have been motivated to do so because PYY belongs to the pancreatic polypeptide family and PYY[3-36] is a

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fragment of PYY, both of which function as inhibitors of pancreatic exocrine, gastric acid, insulin secretion as taught by Yoshinaga et al. (See, e.g., Abstract).

***Claim Objections—Minor Informalities***

7. Claims 23 and 33 are objected to because they either recite unelected subject matter or depend from non-elected claims. Appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].



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All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li  
Examiner  
August 14, 2002



ELIZABETH KEMMERER  
PRIMARY EXAMINER